

## REMARKS

### Status of the Claims

Claims 1-29 were pending.

Claims 1-29 were rejected.

Claims 1, 3, 7, 9, 13 and 14 are amended herein.

Reconsideration is respectfully requested.

### Response to Double Patenting Rejections

Claims 1-29 stand rejected on provisional double-patenting grounds in view of US co-pending application Serial No. 10/055,653, assigned to the present assignee. Although this is a provisional rejection, for the Examiner's information applicant advises that a Notice of Allowance has issued in the '653 application and the issue fee has been paid. Thus, the grant of a patent is soon expected.

With the amendments to the claims herein, the claims of this case are not co-extensive in scope with the claims in the '653 case, such that the double-patenting rejection is of the obviousness-type that can be overcome with a terminal disclaimer. The undersigned represents that upon notice that the claims herein are otherwise in allowable form (i.e., save for the double-patenting rejection), a terminal disclaimer will be filed by the undersigned disclaiming the term of any patent granted from this application past the expiration of the patent granted on the '653 application.

Additionally, claims 15-29 herein stand rejected for obviousness-type double patenting over US Pat. No. 6,576,651B2, assigned to the present assignee, in view of US Pat. No. 4,950,432, to Mehta et al. (hereinafter "Mehta"). The Office Action acknowledges that the '651 patent does not recite lyophilized epothilone analogs, but the Office Action argues that lyophilization of the epothilone analogs claimed herein is obvious in view of Mehta. For the reasons discussed below regarding the Section 103 rejection, a *prima facie* obviousness case has not been met. Thus, for the same reasons discussed below, it is submitted that this rejection should be withdrawn.

### Response to Section 103 Rejection

Claims 1-29 stand rejected under 35 USC § 103(a) over US Pat. No. 6,380,395 to Vite et al (hereinafter "Vite," which is assigned to the present assignee) in view of Mehta.

A *prima facie* case of obviousness requires that three requirements must be satisfied: (1) the prior art relied upon must contain some suggestion or motivation for modifying or combining the references; (2) the proposed modifications must have had a reasonable expectation of success; and (3) the references must teach or suggest *all* claim limitations. See *In re Chu*, 66 F.3d 292, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995); *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443, 1444-46 (Fed. Cir. 1992); and MPEP § 2143. The initial burden of satisfying these requirements rests squarely with the PTO. See *Ex Parte Skinner*, 2 USPQ2d 1788, 1789 (Bd. Pat. App. & Inter. 1986); MPEP § 2142.

Regarding the first two elements of this test, both the motivation to combine the references and the expectation of success must be found in the prior art, not based on applicant's disclosure. *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) ("Both the suggestion and the expectation of success must be founded in the prior art"). Considering the well-known phrase that "hindsight is 20-20 vision," the urge to apply hindsight with the benefit of applicant's claimed invention must be resisted, as it is improper to use hindsight to pick and choose elements to reconstruct an invention. *Smithkline Diagnostic Inc. v. Helena Labs Corp.*, 859 F.2d 878, 887, 8 USPQ2d 1468 (Fed. Cir. 1988) (one may not "pick and choose ... elements of assorted prior art references to recreate the claimed invention").

Here, the Office Action does not point to any teaching, suggestion or motivation in the prior art that would lead a skilled artisan to combine Mehta with Vite to be in possession of applicant's claimed invention, or which would establish a reasonable expectation of success with such a combination. There is no motivation to combine the references. The Office Action notes that Mehta involves use of antibiotic compounds that are administered only orally, and that Mehta teaches preparing liposome-encapsulated macrolide antibiotics and making of a lyophilized powder of antibiotics. In contrast, the instant case involves epothilone analogs, a new class of chemotherapeutic agents which may also be administered parenterally. The structure of the epothilone analogs herein is much different than the structure of the antibiotics in Mehta, and the mechanism of action and utility of the compounds is much different. There is no basis for a comparison of these compounds, no basis in the prior art to find a motivation to combine these references, and no basis to find a reasonable expectation of success. To the contrary, one skilled in the field considering the Mehta reference likely would be doubtful that lyophilization procedures would work for the

epothilone analogs claimed herein, given the difference in structure and utility for these compounds.

Moreover, the third element for a *prima facie* obviousness also is not met. All claim limitations are not met by the combination of references proposed in the Office Action. Indeed, the Office Action acknowledges as much by stating that "Mehta does not teach instant epothilone analog or the exact steps of lyophilization claimed or the claimed Lactated Ringer's injection." The Office Action argues that these matters are "routine optimization within the scope of the skilled artisan." (OA at p. 6.). This is a conclusory statement that lacks any factual or legal support. The term "routine optimization" may be appropriate in cases where, for example, the prior art discloses a temperature range of 50 to 100°C, and a latter applicant attempts to claim the exact same process with an optimized temperature of 100°C. However, "routine optimization" is not an appropriate characterization for entirely new process steps, reaction parameters, ingredients, and reaction conditions.

Additionally, applicant traverses this rejection MPEP 2144.03.

For the foregoing reasons, it is submitted that a *prima facie* case has not been made and all Section 103(a) rejections should be withdrawn.

#### **SUMMARY**

It is believed that all rejections of the claims have been addressed and that the instant claims are in condition for allowance. The Examiner is invited to contact the undersigned if it is believed a telephonic communication would expedite the prosecution of this application.

Respectfully submitted,



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